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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,476	03/11/2004	Thomas L. Cantor	532212000100	8385

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
11/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,476	CANTOR, THOMAS L.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,13,14 and 17-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,13,14 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendments filed 29 August 2007 and 10 September 2007 have been entered in full. Claims 8-12, 15, 16, 24-47 are canceled. Claims 1-7, 13, 14, 17-23 are pending and under examination.

Withdrawn Objections And/Or Rejections

The specification is in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations.

The rejection to claims 1-7, 9, 10, 17-21 under 35 U.S.C. 102(b) as being anticipated by Motte et al. (The Journal of Immunology, Vol. 138, 3332-3338, No. 10, May 1987), as set forth at pages 3-5 of the previous Office Action (17 April 2007), is *withdrawn* in view of the amendment (29 August 2007).

The rejection to claims 1-9, 11, 13, 14, 17-23 under 35 U.S.C. 102(b) as being anticipated by Hutchison et al. (WO 03/003986 A2), as set forth at pages 5-6 of the previous Office Action (17 April 2007), is *withdrawn* in view of the amendment (29 August 2007).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 13, 14, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al., (The Journal of Clinical and Endocrinology & Metabolism, Vol. 84, No. 11, pages 4287-4290, 1999) in view of Hutchison et al. (reference of record, WO 03/003986 A2).

John et al. teach that excess amounts of parathyroid hormone (PTH) fragments are retained in patients with renal failure, which makes it difficult to interpret PTH measurements obtained with radioimmunoassay that use antisera directed against epitopes within the mid or carboxyl terminal regions of PTH. John et al. teach the results of PTH measurements using two different immunoradiometric assays (IRMA) in serum samples. John et al. teach a characterization specificity assay for two antibodies (N-IRMA and S-IRMA). John et al. teach that the specific binding of radiolabeled N-IRMA antibody to hPTH(1-84) was progressively and equally reduced by increasing concentrations of hPTH(1-34) peptide and hPTH(2-34) peptide. In contrast, the S-IRMA radiolabeled antibody was reduced by hPTH(**1**-34) peptide, but not by hPTH(**2**-34) peptide (i.e. a specific amino acid residue dependent antibody, which targets PTH). John et al. teach that the results indicate that the S-IRMA selectively detects human PTH with an intact amino-terminus. John et al. do not teach immunizing a mammal with an immunizing protein or peptide comprising target protein or peptide or purifying an antibody from a mixture of antibodies.

Hutchison et al. teach monoclonal or polyclonal antibodies which recognize PTH (page 1 and page 19, lines 22-35). Hutchison et al. teach that the antibodies will

recognize an amino acid sequence from Ser at position 1 to Leu at position 13 of PTH or combinations thereof or in regions consisting of amino acids 14 to 84 or 13 to 34 (page 16). The PTH antibodies are produced by immunizing animals with intact PTH, variants thereof, or mixtures thereof (page 17, lines 15-32 and page 29, lines 11-32). The PTH antibodies are isolated by exposing sera to antibody affinity purification columns. Solid columns are linked with various PTH peptides, including hPTH amino acid residues 1-13, 13-34 and 39-84 (page 18, lines 15-34 and page 30). Hutchison et al. teach an assay wherein an antibody is immobilized on a solid phase (capture antibody), incubated with an antigen, and further incubated with an antibody with a detectable label (detection antibody) (page 20). Hutchison et al. teach that an antigen can be immobilized on a solid phase incubated with a diluted antiserum or a purified antibody and detectable label, thereby obtaining a labeled binding substance. Hutchison et al. teach a method wherein an antibody is labeled with a detectable label and the other antibody is allowed to bind to a solid phase as a solid phase antibody or is made to be able to specifically bind to a solid phase (capture antibody). The antibodies are allowed to react with antigens in various concentrations to form a plurality of antigen-antibody complexes. Since the antigen-antibody complexes are solid phases, the solid phases are separated from the complexes, and the amount of label in the solid phases is measured. The relationship between the label and the concentration of the antigen is plotted to obtain a standard curve (page 21). Hutchison et al. teach the isolation of antibodies to PTH1-13. Each of the PTH peptides (1-12, 13-34, 38-84) was coupled to sepharose. Goat immune serum was sequentially purified on the affinity

columns to first remove anti-PTH38-84 antibodies, then anti-PTH13-34 and then anti-PTH1-13 antibodies (pages 30-31). Hutchison teaches that anti-PTH1-13 antibodies are labeled for detection and anti-PTH39-84 antibodies are labeled for capture. Hutchison et al. teach that the capture and detection antibodies sandwich the PTH molecules in the sample. The sandwich complex is bound to streptavidin-coated magnetic particles. Hutchison teaches the inhibition of certain PTH peptides (page 33, lines 24-33; page 35, lines 19-29 and page 36, lines 4-19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of identifying a specific amino acid residue dependent antibody to target PTH as taught by John et al., by immunizing a mammal with an immunizing PTH peptide and purifying a PTH antibody from a mixture of antibodies, as taught by Hutchison et al. with a reasonable expectation of success. The motivation and expected success is provided by the general knowledge to one of skill in the art that antibodies are made by immunizing a mammal (with a specific peptide) and then must be purified from a mixture of antibodies (i.e. sera).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

RMD
11/5/07